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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,393	02/18/2004	Mark Laurence Brader	X-10097A	1897

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,393	BRADER ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 27-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 27-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 have been cancelled. Claims 27-42 have been newly added.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-28 and 40-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,922,675. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical formulations claimed in Baker et al. ('675) are encompassed by the claims of the instant application. As such, the claims of the patent and application are directed to overlapping embodiments.

Claims 27-28, 35, and 40-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 4, 23-28, and 32 of U.S. Patent No. 6,444,641. Although the conflicting claims are not identical, they are not patentably distinct from each other because the acylated insulin analogs claimed in Flora. ('641) are encompassed by the claims of the instant application. As such, the claims of the patent and application are directed to overlapping embodiments.

Claims 27-28, 35, and 40-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,335,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical formulations claimed in Hughes et al. ('316) are encompassed by the claims of the instant application. As such, the claims of the patent and application are directed to overlapping embodiments.

Applicant is requested to identify any other co-pending applications with claims directed to compositions of fatty acid-acylated insulin or fatty acid-acylated insulin analogs containing zinc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 and 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 has recites a composition comprising a particular insulin AND a particular insulin analog. Claim 28 upon which it depends is directed to a composition comprising insulin OR an insulin analog. As such, this claim and those that depend upon it are improperly dependent and confusing.

Likewise, claim 35 has been amended to be directed to a composition comprising a particular insulin AND a particular insulin analog. Claim 27 upon which it depends is directed to a composition comprising insulin OR an insulin analog. As such, this claim is improperly dependent and confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-28, 35, and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandenburg et al. (U.S. Patent No. 3,907,763).

Brandenburg et al. discloses insulin derivatives having substituents at Lys B29 from 1 to 15 carbons in length. The derivatives can be crystallized from solutions containing zinc salts. (See at least claim 27; Example 1; colum2, line 44, through column 3, line 15; and column 8, lines 48-50.) The instant specification indicates that any derivative having a carbon atom chain length of at least 6 would be considered a fatty acid. Myristic acid (C14) is within the carbon atom chain length disclosed.

Claims 27-28 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Smyth (U.S. Patent No. 3,868,357).

Smyth teaches B29 substituted insulin derivatives. Acyl groups are especially convenient blocking groups. It is preferred that substituents contain no more than about 6 to about 8 carbons. The insulin derivatives can be formulated with zinc and in solution at physiological pH. (See column 1, lines 37-42; column 2, lines 20-21 and 46-47; column 3, lines 37-60; and column 5, table.) The instant specification indicates that any derivative having a carbon atom chain length of at least 6 would be considered a fatty acid.

Claims 27-32, 34-35, and 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (U.S. Patent No. 5,922,675).

Baker et al. has claims to acylated insulin analogs and zinc. An acylated insulin analog where B30 is Thr is taught and claimed. Acylated Lys at position B29 is disclosed. Myristic acid (C14) is disclosed. (See claims and columns 2-4.)

Claims 27-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Havelund et al. (U.S. Patent No. 5,750,497) or Havelund et al. (U.S. Patent No. 6,011,007) or Havelund et al. (U.S. Patent No. 6,869,930).

The '007 patent is a continuation-in-part of the '497 patent. The '930 patent is a dvision of the '007 patent. All sets of claims are directed to overlapping subject matter that anticipates the instant claims.

Havelund et al. ('497) discloses and claims compositions comprising fatty acid acylated insulin and zinc. The claims encompass normal or naturally occurring forms of insulin as defined by the instant specification as well as analogs. The lysine at position B29 is acylated. The compositions may be aqueous and contain a preservative. The aqueous composition may be between pH 6.5 and 8.5. The composition may contain additional insulin or insulin analogues that are not acylated. (See claims.) The specification indicates that the preservative may be phenol or m-cresol. (See column 15, lines 53-55.) Soluble zinc acetate solution was used. (See Example 28, column 31.) Havelund et al. does not appear to disclose the amount of zinc present in mole/mole terms; however, absent evidence to the contrary, it appears that these limitations would be met. Havelund et al. does not appear to disclose the concentration of the phenolic compound present; however, absent evidence to the contrary, it appears that these limitations would be met. Havelund et al. does not appear to disclose the mole ratio of acylated to unacylated components; however, absent evidence to the contrary, it appears that these limitations would be met given the broad range presently claimed.

Claim 39 of the '007 patent and at least Examples 15 and 18 of the '497 patent teach myristoyl derivatives of insulin. Acylated des (B30) and B30 where B30 is Ala or

Thr human insulin analogs are also disclosed. Zinc is present in the compositions. The ε-amino group of Lys^{B29} is substituted with a lipophilic substituent. The pH ranges and amounts recited in the claims are taught. Presence of glycerol, buffers, and preservatives such as phenol are taught. See for example, column 6, Table 2, and claims of the '007 patent. See also at least claims 1, 18, 35, 38, 40, 42, and 52-53 of the '930 patent.

This application is a continuation of 08/484,542. In this parent application, several declarations under 1.131 were submitted in order to antedate references such as Baker et al. (U.S. Patent No. 5,693,609) as well as Havelund et al. (WO 95/07931). Notably zinc is not recited as a limitation in the '609 patent claims and as such a 1.131 declaration would be permissible for the present claims. Havelund et al. is not a U.S. patent and as such a 1.131 declaration would be permissible for the present claims. Applicant is requested to submit copies of these declarations to complete the file and to avoid having this art applied against the instant claims.

Applicant is reminded that a 1.131 declaration is not proper where the prior art is a patent claiming the same invention as applicant. Applicant is directed to MPEP 2305 regarding priority showings and in particular 37 CFR 41.202(d)(1).

Applicant is further advised that claims specifically directed to myristic acid or myristoyl were not presented prior to the response filed 4/29/03 in parent application 08/484,542. As such, these claims could be rejected under 35 U.S.C. 135(b) as not being made prior to one year from the date on which U.S. Patent

5,750,497 and 6,011,007 were granted. See *In re McGrew*, 120 F. 3d 1236,1238, 43 USPQ2d 1632, 1635 (Fed. Cir. 1997) where the Court held that the application of 35 U.S.C. 135 (b) is not limited to *inter partes* interference proceedings, but may be used as a basis for *ex parte* rejections. See also MPEP 2304.02(c).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen

Marianne P. Allen
Primary Examiner
Art Unit 1647

9/11/05

mpa